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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/563,540

12/22/2005

Jun Nakayama

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EXAMINER

POHNER, STEVEN C

ART UNIT

PAPER NUMBER

1634

NOTIFICATION DATE

DELIVERY MODE

02/25/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/563,540	Applicant(s) NAKAYAMA ET AL.	
	Examiner Steven C. Pohnert	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/19/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of group I, claims 1-8, in the reply filed on 11/30/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The restriction requirement has been made final,
2. Claim 9 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/30/2007.

Information Disclosure Statement

The information contained International search report for has been considered however since there is no publication date, it cannot be printed on the face of patent and therefore a line has been crossed through.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting pancreatic cancer or gastric cancer in human patients comprising: obtaining a peripheral blood sample,

isolating DNA from the blood sample, performing quantitative RT-PCR on the isolated DNA so as to amplify a fragment consisting of nt 520 to 628 of SEQ ID 1, detecting the presence of the fragment using a detection probe, labeled at the 5' end with FAM and the 3' end with TAMURA, using GAPDH as an internal control, determining the expression level of SEQ ID NO 1 by dividing the level of SEQ ID NO 1 by the level of GAPDH and multiplying by 10^7 , wherein a value of 60 or greater for the expression level of SEQ ID No 1 is indicative of pancreatic or gastric cancer, does not reasonably provide enablement for the detection of "any" cancer, by the use of "any" bodily fluid in "any" living body or the determining the degree of pancreatic cancer progression by the use of "any" bodily fluid in "any" living body. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors have been described by the court in *re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in the *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence of working examples, (4) the nature of the

invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.”

The nature of the invention and the breadth of the claims:

The claims are broadly drawn to a method of detecting “any” cancer by measuring the “any” expression level of SEQ ID NO 1 with probes of 70 to 139 base pairs in length in “any” bodily fluid from “any” living body.

Claim 3 encompass detection of one or more cancers selected from the group consisting of salivary gland cancer, esophageal cancer, stomach cancer, pancreatic cancer, gallbladder cancer, small intestine cancer, colon cancer, and rectal cancer.

Claim 6 encompasses a method of determining the degree of progress of of pancreatic cancer by measuring the “any” expression level of SEQ ID NO 1 with probes of 70 to 139 base pairs in length in “any” bodily fluid from “any” living body.

Claims 3 and 8 draw the bodily fluid to blood or lymph.

The amount of direction or guidance and the Presence and absence of working examples.

The specification teaches, “JP 2001 46077 A and (Shimizu) Lab. Invest., Vol. 83, No. 2 (2003), 187-197 disclose an enzyme that transfers GlcNAc to a mucin-type sugar chain by an α -1,4 linkage and DNA thereof, and also disclose a technique for applying the gene to a methyl of detecting cancer based on different expression level of said

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gene in stomach cancer or pancreatic cancer” (0002). The specification thus teaches the gene and its association with pancreatic and gastric cancer were previously known.

The specification further teaches their method improves the sensitivity by detection of a narrower region of SEQ ID NO 1 than was disclosed in Shimuzu or JP 2001 46077 A.

The specification further teaches a study comparing the expression of SEQ ID NO 1 in healthy volunteers, chronic pancreatitis patients and pancreatic cancer patients (example and figure 1).

The specification further teaches a variation in the expression of SEQ ID No 1 relative to GAPDH mRNA expression is less than 12×10^{-7} in a healthy individual or higher relative in a person in which cancer is present (0011).

Further the specification asserts that the measurement of SEQ ID No 1, but the instant invention detected varying values with progression of pancreatic cancer (0014). The specification asserts, “expression levels of the α 4GnT gene and the GAPDH gene (as an internal standard gene) are measured using a body fluid, particularly preferably peripheral blood, to calculate a value by multiplying the ratio thereof by 10^7 , the degree can be defined as Stage IV if the measurement value is 35 or more, the degree can be defined as Stage III if the measurement value is 15 to 35, and the degree can be defined as Stage II if the measurement value is 13 to 15. The ranges of the numerical values (critical values) of the ratio can be appropriately adjusted if necessary” (0014).

The specification teaches DNA was isolated from blood samples of 55 pancreatic cancer patients, 10 chronic pancreatitis patients and 70 healthy volunteers(0019). The

specification further teaches quantitative PCR was done using SEQ ID NO 3 and 4 as primers and SEQ ID NO 5 as a Taqman probe (0020).

The specification further teaches, "Quantification was performed by the multiplex PCR method in which measurement is performed by amplifying a part of the α 4GnT gene using the above-described primers and probe, as well as the cDNA of glyceraldehyde-3-phosphate dehydrogenase (here in after also referred to as "GAPDH") as an internal standard gene, and a numerical value calculated by multiplying "the copy number of amplified products of α 4GnT /the copy number of GAPDH" by 10^7 was defined as the "expression level of α 4GnT " (hereinafter simply referred to as "expression level")(0023)".

The specification further teaches, "As a result, the positive ratio among the entire pancreatic cancer patient group was I found to be 76.4, while the expression level was found to be 35.7 ± 4.9 . In addition, the numbers of pancreatic cancer-positive patients in each disease stage were found to be 0/1 for Stage 0 (a state where cancer cells are localized in the epithelium patient (0%), I (intraepithelial carcinoma)), 2/3 patients (66.7%) for Stage II, 6/8 patients (75.0%) for Stage III, and :34/43 patients (79.1%) for Stage IV, while the expression levels were found to be 24.8 ± 12.5 for Stage II, 29.9 ± 9.2 for Stage III, and 38.34 ± 5.9 for Stage IV and were apt to increase with progression of the disease stage (Table 1). " (0023)

The specification further teaches that the expression levels in healthy volunteers was 7.2 and chronic pancreatitis patients was 17.8 ± 6.9 . The specification further

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teaches there is a significant difference between the chronic pancreatitis and pancreatic cancer group.

It is further noted all the values are much higher than the 12×10^{-7} expression level cutoff discussed in paragraph 11, thus in view of the teachings of paragraph 11 all subjects would have cancer.

It is noted that although there is a difference between the chronic pancreatitis and the whole pancreatic cancer group, the values for the Stage II pancreatic cancer group (24.8 ± 12.5) and chronic pancreatitis overlap (17.8 ± 6.9), thus it would be unpredictable to differentiate between the Stage II pancreatic cancer group and chronic pancreatitis based on this method.

Further the specification does not teach Stage I, pancreatic cancer.

Further the specification does not teach detection in any non-human living body.

Further the specification teaches only detection in blood, but not lymph or any other tissue.

Further the specification provides no data to back up the assertion the instant method is more sensitive than the methods of Shimuzu or JP 2001 46077 A.

The state of prior art and the predictability or unpredictability of the art:

Nakayama et al (JP 2001-046077, published 2-20-2001) claims a method of detecting gastric or pancreatic cancer in blood from a living body by the presence of SEQ ID NO 1 (claims 17-19). Nakayama teaches peripheral blood DNA was isolated from 29 patients with gastric and pancreatic cancer and 10 healthy controls and RT-

PCR analysis was done (example, 0110). Nakayama et al teaches the RT-PCR resulted in the gastric cancer patients but not the controls (0111).

Nakayama further teaches peripheral blood samples of patients with other cancer including esophagus, large intestine, lung and liver did not contain assayable amounts of α 4GnT (0111). Nakayama thus teaches it is unpredictable to diagnose any cancers other than pancreatic and gastric cancer by this method.

Shimizu et al (Laboratory investigation (2003) volume 83, pages 187-197) teaches a method of detecting Gastric cancer by real time RT-PCR of SEQ ID NO 1 (see title, abstract). Shimizu teaches RT-PCR and normalization of GAPDH followed by multiplication by 10^7 was used to examine the presence of SEQ ID No 1 in peripheral blood. Shimizu teaches in figure 3 that patients with gastric cancer had a significantly higher expression of α 4GnT, compared to healthy subjects, patients with chronic gastritis and peptidic gastroduodenal ulcers.

Shimizu et al further teaches in table 1 that tumor stage was significantly correlated with α 4GnT expression. However, it appears that as noted with Nakayama the Stage 1, and Stage II expression appear to overlap with non-cancer patients and thus it would be unpredictable to stage these levels of cancer based on these data.

Shimizu teaches that α 4GnT transcripts were not observable in peripheral blood of patients with esophageal cancer, lung cancer, breast cancer or uterine cancer (page 191, 1st column, last paragraph). Thus Shimizu teaches that the presence of α 4GnT transcripts in peripheral blood is not predictable associated with “any” cancer.

Nakayam et al (Proceeding National Academy of Sciences (1999) volume 96, pages 8991-8996) teaches northern blot analysis of α 4GnT demonstrated that it was not expressed in lymph nodes, peripheral blood leukocytes or bone marrow (see figure 3).

Brenner et al (Trends in Genetics (2001) volume 17, pages 414-418) teaches that, "Here, the 'homology-implies-equivalency' assumption is restricted to a subset of homologs that diverged in the most-recent common ancestor of the species sharing the homologs. This strategy is useful, of course. But it is likely to be far less general than is widely thought. Two species living in the same space, almost by axiom, cannot have identical strategies for survival. This, in turn, implies that two orthologous proteins might not contribute to fitness in exactly the same way in two species" (see page 414, 3rd column last full paragraph). Brenner specifically describes that although the leptin gene homologs have been found in mice and humans, their affect is different (see page 414, 3rd column last paragraph-3rd column page 415). Brenner specifically teaches that the leptin gene in mice plays a major role in obesity, but no such effect has been demonstrated in humans due perhaps to the different evolutionary forces. Brenner thus teaches that the activity and function of genes in different species is unpredictable. Thus in view of Brenner it would be unpredictable to associate the presence of α 4GnT transcripts in "any" living body, as α 4GnT homologs in other living bodies may not have different functions and have the same effect.

The level of skill in the art:

The level of skill in the art is deemed to be high.

Quantity of experimentation necessary:

In order to practice the invention as claimed one of skill in the art would have to determine if expression of α 4GnT transcripts is predictable of "any" cancer. In view of the teachings of Shimizu (page 191, 1st column, last paragraph) and Nakayama (0111) it would be unpredictable to associate the detection of α 4GnT with any cancer other than pancreatic and gastric cancer.

Next the artisan would have to determine have to determine what expression level is required to determine the presence or absence of cancer. This would be unpredictable as the specification teaches that patients with chronic pancreatitis had increased levels of α 4GnT relative to healthy controls and the values of patients with chronic pancreatitis overlapped with those with Stage II pancreatic cancer. It would further be unpredictable as Shimizu teaches patients with peptidic gastroduodenal had elevated levels of α 4GnT transcript that were similar to the levels of stage I and Stage II gastric cancer.

Further the artisan would have to determine if expression of α 4GnT in any bodily fluid including, blood, saliva, urine, sperm, etc, is indicative of cancer. The specification and art have provided any indication that increased expression α 4GnT in any sample other than blood is indicative of "any" cancer.

Next the artisan would to determine if the expression of α 4GnT transcript in "any" living body is predictable with cancer. This would be unpredictable as the specification and art do not teach or suggest that such a relationship exists in any species other than humans. Further there is not teachings in the specification or art of

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record that α 4GnT is present in any other species. Finally in view of the teachings of Brenner, even if α 4GnT is present in any other species there is no teaching or suggest that it has the same function and thus would be correlated with the presence of "any" cancer.

Therefore, in light of the breadth of the claims, the lack of guidance in the specification, the high level of unpredictability in the associated technology, the nature of the invention, the negative teachings in the art, and the quantity of unpredictable experimentation necessary to practice the claimed invention, it would require undue experimentation to practice the invention as claimed.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakayama (JP 2001-046077, published 2-20-2001) .

The claims are drawn to detecting an arbitrary region consisting of continuous nucleotides having a length of 70 to 139 base pairs of SEQ ID NO 1, or specifically nucleotides 520-628 of SEQ ID NO 1. Thus the claims are anticipated by any teaching or claims to the detection of the full length of SEQ ID NO 1, as detection of the full length of SEQ ID No 1 would include detection of the regions of the claims.

Nakayama (JP 2001-046077, published 2-20-2001) claims (claims 17-19) a method of detecting gastric or pancreatic cancer in blood from a living body by the presence of DNA claimed in any of claims 6-12. Nakayama claims in claims 6-12 the DNA encoding a-1,4-N-acetyl glucosamine transferase, the DNA encoding a fragment of the protein and the sequence of nucleotides 181-1200. Nakayama teaches the sequence of a-1,4-N-acetyl glucosamine transferase on page 24 and 25 of detailed description.

Thus Nakayama anticipates a method of detecting gastric or pancreatic cancer by detection of a region consisting of continuous nucleotides having a length of 70 to 139 base pairs of SEQ ID NO 1, or specifically nucleotides 520-628 of SEQ ID NO 1..

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakayama (JP 2001-046077, published 2-20-2001) in view of Gelfand (US Patent 5,487,972 issued Jan 30, 1996).

This rejection is drawn to the narrow scope of detecting pancreatic or gastric cancer by detection of SEQ ID NO 1 or α 4GnT mRNA in peripheral blood. This rejection in anticipation that claims are amended to require detection of only 73 to 139 bases of SEQ ID No 1 or only nucleotides 520 to 628 of SEQ ID NO 1.

Nakayama (JP 2001-046077, published 2-20-2001) claims (claims 17-19) a method of detecting gastric or pancreatic cancer in blood from a living body by the presence of DNA claimed in any of claims 6-12. Nakayama claims in claims 6-12 the DNA encoding α -1,4-N-acetyl glucosamine transferase, the DNA encoding a fragment of the protein and the sequence of nucleotides 181-1200. . Nakayama teaches the sequence of a-1,4-N-acetyl glucosamine transferase on page 24 and 25 of detailed description.

Gelfand et al. teaches a process of detecting a target nucleic acid using primers and probes in a PCR amplification assay (abstract). Gelfand teaches his method allows the amplification and detection of amplified products with minimal post-amplification handling (see column 2, lines 10-15). Gelfand et al. teaches a method comprising

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providing a set of oligonucleotide primers and amplifying the target nucleic acid sequence in a PCR reaction annealing both the primers and a labeled probe, and detecting the release of labeled fragments to determine the presence or absence of target sequences in the sample (column 2, lines 46-67 and column 3 lines 1-10).

Gelfand et al. provides guidance in the choosing of primers.

“The primer must be sufficiently long to prime the synthesis of extension products in the presences of the agent for polymerization. The exact length and composition of the primer will depend on many factors, including temperature of the annealing reaction, source and composition of the primer, proximity of the probe annealing site to the primer annealing site, and ration of primer: probe concentration. For example, depending on the complexity of the target sequence, the oligonucleotide primer typically contains about 15-30 nucleotides, although a primer may contain more or fewer nucleotides. The primers must be sufficiently complementary to anneal to their respective strands selectively and form stable duplexes” (Column 8 lines 21-34).

Gelfand further teaches the use of interactive labels on a single oligonucleotide probe (see column 11, lines 10-15).

Designing primers and/ probes, which are equivalents to those taught in the art is routine experimentation. The prior art teaches the parameters and objectives involved in the selection of oligonucleotides that function as probes, see Gelfand, column 8, lines 21-24. The prior art is replete with guidance and information necessary to permit the ordinary artisan in the field of nucleic acid detection to design primers and probes. As discussed above, the ordinary artisan would be motivated to have designed and tested

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new probes to obtain additional oligonucleotides that function to detect specific SEQ ID NO 1 and identify oligonucleotides with improved properties. Thus, for the reasons provided above, the ordinary artisan would have designed additional probes primers using the teachings in the art at the time the invention was made. The claimed SEQ ID NO 1 are obvious over the cited prior art, absent secondary considerations.

Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to detect SEQ ID NO 1 in peripheral blood for the detection of pancreatic or gastric cancer. The skilled artisan would be motivated to use the guidance of Gelfand to produce primers and probes of any length or region of the nucleic acid sequence taught by Nakayam, as Gelfand teaches his method allows amplification and detection with minimal additional handling. The skilled artisan would have a reasonable expectation of success as Gelfand and Nakayama are both drawn to methods of detecting nucleic acids. The primers and probes designed by the combined teachings of Gelfand and Nakayama would result in primers and probes that would render methods of detecting only 73 to 139 bases of SEQ ID No 1 or only nucleotides 520 to 628 of SEQ ID NO 1 obvious, absent secondary considerations.

Summary

NO claims are allowed

Conclusions

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven C. Pohnert whose telephone number is 571-272-3803. The examiner can normally be reached on Monday-Friday 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Steven Pohnert

/Ram R. Shukla/
Supervisory Patent Examiner, Art Unit 1634